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Susan L. Eick

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re: Sethi et al.

Examiner: Louise Leary

Serial No.: 09/780,503

Art Unit: 1654

Filed: February 9, 2001

For: A Method of Detecting Bacterial Exacerbations of Chronic Lung Disease

**37 C.F.R. 1.131 Declaration**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The undersigned, Sanjay Sethi, declares:

1. That he is an Associate Professor in the Department of Medicine at the State University of New York in Buffalo;
2. That he is an inventor on the above-referenced patent application.
3. That he is familiar with the Office Action mailed on May 13, 2003 in which some claims were rejected as obvious over Tsang et al. (Chest, 117:420-426, February 2000).
4. That the present invention relating to a method of detecting bacterial exacerbations of chronic lung disease by determining sputum elastase, a method of detecting H. influenzae induced exacerbations of chronic lung disease by determining sputum IL-8 levels and a method of detecting H. influenzae or M. cattarhalis induced

exacerbations of chronic lung disease by determining sputum TNF- $\alpha$  levels was made prior to February 1, 2000, as evidenced by the accompanying abstract published in March 1999 in the American Journal of Respiratory and Critical care Medicine, vol. 159, no. 3, page A822.

5. That all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Respectfully submitted,

7/29/03  
Date

Sanjay Sethi M.D.  
Sanjay Sethi, M.D.